National Coalition of Food Importing Associations

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Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Resources
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0278 – Comments On Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir/Madam:

The National Coalition of Food Importing Associations (NCFIA or "the coalition") is pleased to submit comments to the Food and Drug Administration (FDA) on the FDA's notice of proposed rulemaking, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5428 (Feb. 3, 2003) (hereinafter Prior Notice Proposed Rule).

NCFIA is a coalition of trade associations that represent different segments of the food importing community. Members of NCFIA include the following associations: American Spice Trade Association, Cheese Importers Association of America, Association of Food Industries, The Cocoa Merchants' Association of America, and the National Fisheries Institute (NFI). Companies belonging to NCFIA members annually import over $13.5 billion in food products.

NCFIA commends FDA for working so quickly to implement the provisions of the Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). Further, NCFIA shares the agency's goals of assuring that the United States' food supply is and remains safe and wholesome. Yet, NCFIA has grave concerns regarding numerous aspects of the Prior Notice Proposed Rule. Most fundamentally, NCFIA questions the extent to which the many burdensome aspects of the proposed rule further the goals of the Bioterrorism Act. NCFIA also comments upon the following:

- The failure of the Prior Notice Proposed Rule to account for different modes of transportation and types of food;
- The Prior Notice Proposed Rule's duplication of existing reporting requirements;
- The flawed economic analysis upon which the Prior Notice Proposed Rule rests;

- The limitations upon amendment of previously filed prior notices;
- The flaws in FDA's assumption that most information the prior notice would require is known or fixed;
- The need for clarification of the grower identification provisions;
- The need for clarification of the "article of food" definition;
- The period of prior notice FDA is mandating;
- The failure of FDA to provide for appeal procedures;
- The failure of FDA to allow for practice of a back-up system; and
- The failure of the proposed information system to provide for any form of verification of submitted information.

These issues are addressed below. NCFIA has previously submitted comments to this docket and to the Office of Management and Budget on the Paperwork Reduction Act burdens of the Prior Notice Proposed Rule. NCFIA incorporates those comments here.

I. INTRODUCTION

1. Summary Of Recommended Changes To The Prior Notice Proposed Rule

NCFIA recommends that FDA incorporate the following changes, among others, into the final Prior Notice Rule:

- Adopt a four hour prior to entry prior notice requirement with ability to amend up to two hours after arrival of the entry (this is needed for air cargo that is not released to importer/consignee until then – for many shipments this will be the earliest time to confirm quantity and identity information);
- Adopt a prior notice requirement that does not mandate (except for grower identification, when known) more information than the U.S. Customs Service (Customs) requires;
- Reduce the amount of information that must be included in the prior notice so as to be consistent with the Bioterrorism Act;

- Tailor prior notice requirements to accommodate different modes of transportation (rail, vessel, air, truck) and different food products (perishable, non-perishable, short and limited shelf life, temperature sensitive, etc.);

- Obtain from and coordinate with Customs on day, time, and port of entry information;

- Limit grower identity information to known growers of raw agricultural products;

- Clarify and limit "article of food" definition;

- Provide for verification or validation of prior notice entries; and

- Allow for back-up system practice.

2. The Purpose of Prior Notice

Section 307 of the Bioterrorism Act imposes a new, but limited, requirement upon those who import articles of food into the United States. FDA, after consultation with Customs, shall require that a notice be submitted to the agency requiring identification of the following prior to importation:

- The article;
- The manufacturer;
- The shipper;
- If known within the time the notice is required to be provided, the grower of the article;
- The country from which the article originates;
- The country from which the article is shipped; and
- The anticipated port of entry.

21 U.S.C. § 381(m)(1). The purpose of this provision is a very limited one and is set forth in the statute: "[to enable] such article to be inspected at ports of entry into the United States." 21 U.S.C. § 381(m)(1). The notice prior to import is solely to allow FDA to make a determination as to whether or not to inspect the article before it enters United States commerce.

As FDA reviews the Prior Notice Proposed Rule in light of the many comments it will receive, NCFIA urges the agency to consider the extent to which the multitude of requirements FDA proposes to mandate are truly in furtherance of the limited purposes Congress contemplated when it enacted 21 U.S.C. § 381(m).

II. ECONOMIC ANALYSIS AND RELATED ISSUES

1. FDA's Economic Analysis Of the Prior Notice Proposed Rule Is Significantly Flawed

FDA recognizes that the Prior Notice Proposed Rule will require fundamental changes in how the business of the importation of food is conducted. Yet, in making this recognition, FDA fails to consider the costs to the many entities that will find their importing businesses radically altered. Moreover, FDA's calculations of the costs of the rule under different periods of prior notice (4 hours, 8 hours, noon of previous day) are flawed. Also, FDA's calculations of the Prior Notice Proposed Rule's benefits are not applicable to the harms the Prior Notice Proposed Rule is intended to prevent.

a. FDA Underestimates Costs

FDA has emphasized the Prior Notice Proposed Rule will represent a new way of doing business. FDA fails, however, to include many aspects of the costs to achieve this new business reality. For instance, reams of information that have never been collected before will now have to be supplied. Importers, brokers, suppliers, manufacturers, shippers, warehouses, truckers, airlines, ocean carriers, freight forwarders, consolidators, non-vessel operating common carriers, and others will all have different pieces of information that will have to be communicated for the first time, or will have to be communicated in a different way, or at a different time. Because providing this information will be essential to complying with the prior notice requirements, contracts and pricing amongst these entities may have to be renegotiated. In addition, customary business forms and systems will have to be altered. FDA makes no estimate at all of these costs.

Other assumptions by FDA regarding the information collection costs of the Prior Notice Proposed Rule are plainly flawed. FDA assumes only 77,427 filers will need to be educated about the Prior Notice Proposed Rule. 68 Fed. Reg. at 5458, col. 1. The number is much greater for the following reasons, among others:

- FDA assumes only one employee and a supervisor will need to be trained in the new system. It is customary for an importer, depending upon its size, to have at least two trained filers – this is the standard business practice for accomplishing Customs/FDA filings currently. At least two filers, and likely many more, including possibly, an importer's or broker's entire filing staff and supervisors will need to understand the prior notice filing system. Only the smallest of brokers and importers will have as few as two people to train. For many firms, the number will be in the range of four to ten. For the largest firms, the numbers could easily exceed ten.

- Firms will need to educate their suppliers, manufacturers, customers, drivers, suppliers, warehouses, growers, carriers, shippers, and other entities involved the importation of food. As these entities control much of the information the Prior Notice Proposed Rule requires be disclosed, they will need to learn the rule's requirements, even if they have no direct filing responsibilities.

FDA also assumes that there are 4.7 million line entries per year and that each line will require a separate notice. 68 Fed. Reg. at 5435, col. 2 and 5442, col. 2. Yet, FDA calculates that there will be only 1.8 million notices filed per year. 68 Fed. Reg. at 5458, col. 2. FDA, by its own calculations, understates the number of notices to be filed by almost 3 million.

Even this number of line entries is significantly understated given FDA's proposed requirement that each article of food be subject to a separate notice. 68 Fed. Reg. at 5435, col. 2. Among other things, FDA proposes requiring a separate notice for every product size, every product brand name, and for every manufacturer or grower. This is a significant departure from current practice that will multiply the number of prior notices to be filed.

Additionally, NCFIA is informed that import entries currently combine a variety of similar goods (e.g., different sizes, species and brands of shrimp) into one line entry. The Operational and Administrative Systems for Import Support (OASIS) system does not require that a product be broken out beyond the tariff number. The Prior Notice Proposed Rule would require that, in the above example, each size of shrimp be broken out into separate notifications. The effect is to dramatically multiply the number of entries and prior notices to be made.

FDA proposes that only a purchaser or importer who resides or maintains a place of business in the United States, or their U.S. agent would be authorized to file a prior notice. Proposed 21 C.F.R. § 1.285. There are many situations where a foreign seller will import goods into the United States, through a U.S. Customs Broker, where the foreign seller is basically the importer. This practice is very common in the spice, fish/seafood, and processed food areas and with United States buyers who do not wish to have any involvement in the process of importing products. The cost for foreign companies to obtain a U.S. agent authorized to file notices on their behalf will be a significant cost to business that is not included in FDA's cost calculations.

FDA further assumes one hour to learn the rule if the responsible party has Internet access. 68 Fed. Reg. at 5441, col. 3 and Table 1. If the experience of those supporting this comment is any guide, FDA has grossly underestimated the complexity of its proposal. Attorneys who are well-versed in food law and experienced importers and brokers have spent many, many hours reading the Prior Notice Proposed Rule and trying to understand it. Customs brokers have told NCFIA that, at minimum, one-day workshops will be needed to train filers. They use, for reference, the training conducted by FDA for filers when the agency converted to electronic submission for OASIS. Multi-hour workshops were held and had to be offered again due to a huge failure rate. The submission of

prior notice information is more substantial and with greater likelihood of error, thus training will have to be far more extensive than FDA estimates.

Moreover, FDA assumes only 45 minutes of time for a filer to complete the prior notice screens of information. 68 Fed. Reg. at 5442, col. 3 and Table 3.. However, the information required in the Prior Notice Proposed Rule does not reside in a single place at this time. The importer or other filer will have to gather the required information from several entities (broker, customer, shipper, carrier, freight forwarder, manufacturer, supplier, and others). The 45 minutes FDA allots for filing assumes that all the information is in the control of the importer or other filer. This is certainly not the case.

As discussed in more detail below, under current practice much of the new, additional information FDA seeks (and that is beyond the scope of § 307, 21 U.S.C. § 381(m)(1)), resides with different entities, if it exists at all. In the case of, for instance, Automated Commercial System (ACS) numbers, there is no way for the prior notice filer to obtain that information from the broker who will make the Customs entry. The broker generates the ACS number as a by-product of the Customs entry process. Nor does the ACS number exist in a public database that allows for searching and verification.

It will require a significant amount of time to compile the required information, check the information, and obtain missing information. In addition, all entries will need to be subjected to intensive proofreading to assure accuracy of data entry. We estimate the time required for filing to be approximately 2 hours.

The Prior Notice Proposed Rule requires that filers include the estimated day and time of arrival. Proposed 21 C.F.R. § 1.288(k)(1), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives 3 hours later or 1 hour earlier than reported in the notice, the Prior Notice Proposed Rule requires that the filer correct the arrival information. Proposed 21 C.F.R. § 1.288(k)(2), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives outside this 4-hour arrival window, the prior notice is inadequate, the product will be refused, and a new prior notice must be made. Thus, brokers and importers will need to establish operations that operate around-the-clock, 24 hours a day, seven days a week, to assure that if estimated times of arrival suddenly change, the prior notice can be amended. FDA does not estimate the costs for importers, their suppliers, and Customs brokers currently operating with normal business hours, to establish and maintain 24/7 filing operations.

NCFIA understands from filers that they believe it will be necessary to hire additional staff to provide the additional services associated with compliance with the Prior Notice Proposed Rule. NCFIA understands that brokers and other filers are estimating that the cost of each import entry will increase by as much as 70% if the Prior Notice Rule is implemented as proposed. As the average cost of an entry is approximately $110 currently, this means the additional increase in annual

customs brokerage charges that importers (and ultimately, consumers) must bear will exceed $300,000,000 (4.7 million entries X ($110.00 X .7) = $361,900,000).[1]

Furthermore, FDA calculated only the costs of delayed shipments of highly perishable foods -- Canadian and Mexican fresh produce and fish/seafood. FDA failed to calculate the loss associated with delays at the airports when air-shipped seafood and other perishable air cargo arrives from throughout Latin America and Europe. Moreover, the cost of delayed entry is also very significant for non-perishable foods. There will also be storage costs and additional transportation costs for articles of food refused entry due to inadequate notice. FDA did not consider these costs.

In sum, FDA's cost calculations for compliance with the Prior Notice Rule, as proposed, are incomplete and vastly understated.

b. FDA's Estimates Of Costs For 4 and 8 Hour Notice Are Flawed

FDA analyzes the economic impacts of different prior notice deadlines -- 4 hours prior to arrival, 8 hours prior to arrival, and noon of the day before arrival. 68 Fed. Reg. at 5443-5453 and Table 17. FDA determined that the option set forth in the proposed rule, filing by noon of the day prior to port arrival, with one amendment, was the least costly. Yet, FDA did not make a true and accurate comparison of the costs between the option it adopted and the shorter prior notice options it rejected. Specifically, FDA assumed a filer could amend a filed notice only by noon of the day prior to port arrival option; it did not allow an amendment option for the alternative, later prior notice proposals of 4 hours or 8 hours prior to port entry. Had FDA made a true and accurate comparison, the four hour prior notice rule, with one amendment, would have been the most cost effective option.

FDA offers no serious discussion at all of the 4 hour and 8 hour prior notice options. By relying solely upon the inaccurate comparison described above, FDA essentially "stacked the deck" against any option other than its preferred notice to be filed by noon of the day prior to port arrival option. By manipulating the calculations as it did, the noon of the prior day option became a foregone conclusion.

FDA identified the 4 and 8 hour prior notice provisions as alternatives for implementation. It must, therefore, be presumed that these less expensive options (if one amendment is permitted) were otherwise legally sufficient to meet the requirements of 21 U.S.C. § 381(m). In particular, by considering the 4 hour option, FDA had conceded that this implementation alternative would comply with the Bioterrorism Act. The only reason FDA gives for rejecting this legally sufficient alternative

[1] Recall that NCFIA is of the view that FDA has significantly understated the number of entries that will be have to be covered under a single prior notice. FDA's estimate of 4.7 million line entries is likely understated.

is by reliance upon its cost calculations. Yet, as described above, FDA's cost analyses and justification for rejecting the 4-hour rule rests upon an inaccurate comparison.

c. FDA's Initial Regulatory Flexibility Act Analysis Does Not Comply With The Act.

Pursuant to the Regulatory Flexibility Act (RFA), FDA's initial regulatory flexibility analysis was required to contain, among other things, an identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap or conflict with the proposed rule. 5 U.S.C. § 603(b)(5). As discussed in detail throughout this comment, the Prior Notice Proposed Rule overlaps significantly with other federal reporting requirements, including entry information provided to Customs, OASIS information provided to FDA, and other FDA reporting requirements, including the proposed rule requiring registration of food establishments. FDA, however, still proceeds with its proposal to establish a whole new and separate reporting system and provides no more than a cursory recognition that much of the information it would require under the Prior Notice Proposed Rule is already submitted to it via some other mechanism. FDA's failure to delineate the enormous and significant duplication and overlap the Prior Notice Proposed Rule would compel if finalized likely is a fatal deficiency in the FDA's RFA analysis.

Additionally, in contravention of 5 U.S.C. § 603(c), FDA's initial RFA analysis fails to describe any significant alternatives to the Prior Notice Proposed Rule which will accomplish the stated objectives of the Bioterrorism Act and minimize any significant economic impact of the proposed rule on small entities. The agency's initial RFA analysis must discuss significant alternatives such as:

1. The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

2. The clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

3. The use of performance rather than design standards; and

4. An exemption from coverage of the rule, or any part thereof, for such small entities.

21 U.S.C. § 603(c). FDA did not undertake this analysis in the Prior Notice Proposed Rule.

d. FDA Also Miscalculates The Benefits Of the Prior Notice Proposed Rule

FDA looks to the costs of domestic food borne illness outbreaks as a measure of the benefits arising from the Prior Notice Proposed Rule. 68 Fed. Reg. at 5454-5457 and Tables 20-23. These calculations are almost meaningless as their connection to 21 U.S.C. § 381(m)(1) is very weak. NCFIA urges FDA to be more cognizant of the distinction between "food safety" and "food security." Only one of the outbreaks described resulted from imported foods. Moreover, it is not clear at all how, even if the food borne illnesses had all been caused by imported foods, how increased border inspection would have prevented the resulting illnesses and costs. All of the illness and costs from these outbreaks arose from pathogens that could not have been detected through a border inspection. Using such an attenuated estimate of benefits arising from the Prior Notice Proposed Rule seems highly suspect.

III. INFORMATION COLLECTION ISSUES

1. The Information Collection Aspects Of The Prior Notice Proposed Rule Far Exceed The Bioterrorism Act's Purpose

From the seven, straightforward pieces of information the Bioterrorism Act requires be provided (as discussed in section 2 above), FDA constructs a prior notice submission form that is potentially 5 pages long, with hundreds of separate data elements. 68 Fed. Reg. at 5464. In the Prior Notice Proposed Rule, FDA goes far beyond what the Bioterrorism Act requires and far exceeds what is necessary to enable FDA to identify which articles of food offered for import should be inspected.

FDA proposes that the prior notice to be submitted would have to contain information that identifies:

- The individual and firm submitting the prior notice, including:
  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number;
- The entry type and ACS entry number or other Customs identification number associated with the import;

- The location where the article of food is being held, if the article is already on hold due to a previously filed, but inadequate, prior notice.;

- The identity of the article of food being imported or offered for import, including:

  - The complete FDA product code;
  - The common or usual name or market name;
  - The trade or brand name, if different from the common or usual name;
  - The quantity described from smallest package size to largest container; and
  - The lot or code numbers or other identifier of the food if applicable;

- The manufacturer, including:

  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number

- All known growers, including;

  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number;

- The country from which the article originates;

- The shipper, including
  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number;
- The country from which the article of food was shipped;
- The port where Customs entry will be made;
- The anticipated arrival information, including
  - anticipated port of entry;
  - anticipated date of arrival; and
  - anticipated time of arrival.
- The port where entry will be made for Customs purposes;
- The anticipated date of entry for Customs purposes;
- The importer, including:
  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number;
- The owner, including:
  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number;

- The consignee, including:
  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number; and
- All carriers, including;
  - name
  - address
  - phone number
  - fax number
  - E-mail address
  - FDA registration number.

Thus, FDA is seeking far more information than the seven simple data elements set forth in Section 307 of the Bioterrorism Act, 21 U.S.C. § 381(m)(1). Yet, the agency does not explain how demanding so many details will effectuate the purpose of the Bioterrorism Act. Specifically, there is no explanation as to why this information will allow FDA to determine which imports to inspect. FDA states only that it wishes to have this information but does not explain except in the most conclusory of terms, how this information will allow it to perform the functions Congress assigned to the agency under the Bioterrorism Act.

In so doing, the agency also seemingly violates the requirement of the Administrative Procedure Act that proposed rules be accompanied by adequate prior notice. 5 U.S.C. § 553. FDA must explain why it needs information that far exceeds what the statute mandates. Rather than explaining its justification for the information proposed to be required, and allowing industry to comment upon it, FDA essentially shifts the burden of explanation and refutation to the information submitters. The statute does not require the collection of this information; it is FDA, not affected industry, who should be required to put forth a compelling explanation for needing so much information. Before it may so exceed the Bioterrorism Act's requirements, FDA should put forth how all this information, most of it highly redundant of existing government reporting requirements (e.g., Advanced Presentation of Vessel Cargo Manifest Customs (67 Fed. Reg. 51519)), will allow FDA to better perform its mandate of identifying which imports to inspect. FDA should have explained how each data element the agency proposed to require is viewed as a means of enabling the agency to determine whether to inspect the article of food offered for import.

2. The Prior Notice Proposed Rule Duplicates Existing Reporting Requirements Without Attempting To Coordinate With Such Existing Reporting Requirements

The Bioterrorism Act mandates that FDA coordinate with Customs to implement the prior notice rule. FDA has wholly failed in this statutory obligation. Rather than using an existing, proven, and functional information collection system that currently exists with Customs, FDA proposes establishing a brand new system and imposing a second set of notification requirements upon industry.

Under the current system, each FDA district office receives notification from Customs of all entries of articles under FDA jurisdiction at ports of entry located within the district office's territory. The notification is nearly always accomplished through the Automated Broker Interface (ABI). It is our understanding that all licensed Customs brokers participate in the ABI. Through ABI, participating brokers use Custom's ACS for cargo release and, for FDA-regulated product, complete an additional screen of information on FDA's own electronic entry system – OASIS. The ABI/ACS/OASIS System covers almost all imported food.

Entries made through the ABI/ACS/OASIS system include all the required Customs entry information, including entry number, entry date, importer identification, port of entry, vessel/voyage information, filer identification, Harmonized Tariff Schedule (HTS) code(s) for the product described in the importing documents (tariff code), information on the foreign shipper, country of origin, quantity of the articles, and value.

For FDA-regulated products, after the broker completes the Customs information, an additional screen of information appears and the broker makes an electronic filing in FDA's OASIS system. In addition to what is already provided on the ACS screen, the filer provides on the OASIS screen for FDA: (1) the seven character FDA Product Code; (2) the Manufacturer's Identification (MID) code of the foreign manufacturer[2] (3) the MID information of the foreign shipper, including city and country, which may or may not be the same as the foreign manufacturer; (4) the country of origin.

Thus, nearly all of the information 21 U.S.C. § 381(m)(1) mandates is captured by the OASIS/ACS system and interface. NCFIA urges FDA to look again at the existing data capture achieved in the OASIS/ACS submission. Ideally, FDA and Customs could agree to push back by a period of hours the time at which brokers currently make the OASIS/ACS entry. In the absence of better coordination with Customs, the Prior Notice Proposed Rule imposes not only duplicative burdens upon industry, but duplicative burdens upon FDA as well, for FDA will have to review

[2] Customs assigns an MID code for each foreign firm. This code is subsequently transmitted to FDA's OASIS screen as the uncoded name of the identified firm.

information on the same shipment of goods twice, once to determine whether to inspect the goods, and then to determine whether or not the goods should be entered into United States commerce.

In addition, FDA should look to the information capture under way with Customs' recently implemented 24-hour advance manifest regulation which was specifically developed to address the threat of terrorism by identifying "high risk" shipments. Currently shippers must notify Customs of a vessel's manifest, 24 hours prior to loading. Customs is wrestling with promulgating another notification regimen for air and land shipments as well. The vessel rule has had enormous repercussions to trade and Customs had not yet begun to fully unravel and address the problems of diminished supply. NCFIA urges FDA to consult with Customs on whether these shipper notifications could be forwarded to FDA to satisfy the prior notice requirement.

Both the OASIS/ACS and the 24-hour notification prior to loading the vessel, require submission of data. Those submissions would likely satisfy the requirements of Section 307 of the Bioterrorism, 21 U.S.C. § 381(m)(1), but for identification of grower, if known, and possibly also identification of originating country. It seems likely that the existing systems could be modified to include these data elements.

Ideally, the planned Customs Automated Commercial Environment (ACE) will permit the submission of both Customs and FDA information at the same time in a single integrated system. FDA states, however, that the ACE is still many years from implementation. Regardless, until the ACE system is operational, and full data and system integration achieved, NCFIA urges FDA to avoid mandating submission of more data elements than the Bioterrorism Act requires. Another system, the Internet Trade Data System (ITDS), is also under development. It may be possible, once this system is operational, to coordinate prior notice filings through the ITDS.

NCFIA cautions FDA that the prior notice system the agency proposes involves the transfer of large amounts of data over very archaic systems. Customs notification systems already suffer overload, for the systems cannot accept the data fast enough. FDA is proposing new, data-intensive information requirements that old technology can not support; Customs' notifications systems falter and crash, and FDA is proposing to require far more information than Customs requires. Industry is faced with the prospect that imports will be refused entry into the United States because the FDA prior notice system technology will not be able to support and relay quickly enough the vast information FDA is requiring.

NCFIA urges FDA to heed the mandate of the Bioterrorism Act and coordinate the prior notice final rule with Customs.

3. FDA Is Mistaken In Its Assumption That Most Information Is Fixed Or Known At Time Of Purchase Order

FDA contends its lengthy prior notice requirement and limited amendment options are justified because in most circumstances, the information required in the prior notice is generated and known at the time the article is ordered or purchased. 68 Fed. Reg. at 5433, col. 2. In the experience of NCFIA's members, this is frequently not the case. Sometimes, the information can change; in other instances, the information sought for the prior notice is not known and/or does not exist. NCFIA asks that FDA clarify that a prior notice will not be rejected or deemed more suspect for failure to include certain information where that information does not exist.

The importation of fresh fish from Central and South America illustrates the many errors in FDA's assumptions. Typically, an importer or other purchaser will place an order for a variety of fish with the foreign supplier. The supplier will commit to a certain amount and species.

As the fish is caught, the supplier than takes the fish to the airport for shipment to the United States. Frequently, the airplane cannot accommodate all of the shipment. Some of it may be sent on one flight; the remainder on another flight, maybe that day, and maybe another. Even then, the flight information may be wrong, the shipment may have been split among different flights, including different airlines than anticipated, and certainly, the arrival and quantity information provided in the prior notice will be incorrect. To claim simply that the shipper will have to organize its business practices and provide better information is naïve. In the above example, the experience of NCFIA members is that with, for instance, communications from Central and South America, the technology is very antiquated and availability to reliable communications networks can be sporadic. South and Central American and European fresh fish shippers may not have the capability to communicate updated and detailed quantity, species, and arrival information to the importer within the prior notice deadline and the importer will not know until he goes to the airport to pick up the shipment.

NCFIA notes additionally that in the cost calculations for lost value due to refused shipments of fresh fish, FDA assumed that fresh fish was arriving into the United States only by truck. Generally, the most valuable foods are shipped by air. FDA apparently did not compute the enormous losses due to refused shipments of fish arriving by air. The losses to industry from product arriving by air will be very large as well. See Table 7, 68 Fed. Reg. at 5446-5447.

FDA indicates that a prior notice in which an amendment is requested and is subsequently not needed will be considered inadequate/invalid. This is ludicrous for fresh seafood shipments because the importer has no way of knowing whether an amendment is going to be necessary by the submission deadline. Therefore, under the proposed system, the importer will often have to gamble that an amendment will be necessary. This places him at risk of detention at time of arrival. There should be no penalty if the entry does not end up needing to be amended.

The above is only an example of how FDA's assumptions are not grounded in the real business of import practice. NCFIA addresses each of the different prior notice data elements below.

a. The entry type and Customs ACS entry number or other Customs identification number associated with the import

As discussed above, difficulty arises with requiring the Customs ACS entry number. It is generally the broker, not the importer, who generates the number and it is not publicly available. The importer and the broker may be, but are not necessarily, the same entity and there is no mechanism for communicating this information from the broker who generates the number to the importer filing the prior notice. As ACS numbers are generated by a broker's own internal system, there is no public database that records the numbers, nor is there anyway for an importer completing a prior notice form to assure that the number provided is accurate. Moreover, the ACS number would have to be included in the prior notice likely before the broker has even generated it for Customs entry purposes.

FDA also requires identification of the entry type, that is whether the article imported is a "consumption entry," or "warehouse entry," or other type of entry. 68 Fed. Reg. at 5436, col. 1; 21 C.F.R. § 1.288(b). The Bioterrorism Act does not require this information; FDA does not explain why such information will aid FDA's identification-for-inspection functions.

Further, NCFIA members report that Customs entry type can change, yet the Prior Notice Proposed Rule would not appear to permit an amendment to reflect this minor change. It is not uncommon for importers to order an article intending it as a consumption entry, and then, once the product is imported, change the article to a warehouse entry. This occurs, for instance, when an importer has met the allotted quota or license for that article for the year, and must temporarily warehouse the goods. The proposed amendment provisions would not allow the importer to amend the prior notice to reflect this simple, innocuous change. Under the Prior Notice Proposed Rule, the article would be refused entry needlessly, would have to be stored at the port, and the importer would have to file a new notice.

b. The complete FDA product code

There are numerous instances in the trade where the purchaser places a general order in a "pipeline" – for an amount of some class of product to be delivered over a period of time. Under these circumstances, the importer does not know the exact product he is getting, or the amounts, until the products are shipped. Such practices are very common with imported specialty cheeses, for instance, where an overseas cheese consolidator will purchase, according to his or her judgement, the best cheeses available at the time. The importer will not know which particular cheeses the consolidator has selected, nor the amounts, until the consolidator puts the products on the plane. Similar practices are very common with fresh fish and seafood and fruits and vegetables as well.

The importer will not know the species, variety, trade or brand name, quantity, package sizes, or lot or code numbers of the merchandise until it has been shipped.

Such changes and uncertainty mean that the precise product identity, including its complete FDA product code, is not known at the time the importer places the order. FDA should allow for liberal amendments to accommodate this type of business uncertainty and for changes to and clarification of an article's identity.

c. The trade or brand name

It is not uncommon for a single product, which would be subject to a single OASIS line entry and prior notice, to contain multiple brand names. Manufacturers may also have multiple trade names for the same or similar products. The utility of requiring identification of trade or brand name is not clear when the statute does not require it, and the information will likely be confusing if it is obtained.

There are also many imported products that do not have a trade or brand name at all, such as agricultural products, fish and seafood. The final rule should clarify that FDA will not reject an article for failure to include trade or brand information where such information does not exist.

d. The quantity described from smallest package size to largest container

As discussed above, frequently, a purchase order is for delivery of product over a period of time. An importer does not know the amount of product to be shipped on any given day. This flexibility allows for short term commercial uncertainties such as fluctuations in supply, weather, manufacturing problems, personnel changes or illness, transportation problems, inadequate cargo space, and the many other factors that can effect what a foreign supplier is able to ship on a given day.

Frequently, the importer does not even have the detailed package size information the Prior Notice Proposed Rule would require. Currently, with many types of products, multiple package sizes are lumped together in a single ACS line entry on the OASIS form. This problem is substantial for fresh seafood because the fish may not even have been entirely unloaded by the proposed deadline. Therefore, the processor will not know the size of the fish to be cut and/or packed for export. The size of the fish will dictate the size and configuration of the package. FDA should clarify how departing from the current practice is necessary to further its inspection identification mandate.

Additionally, with some products that, for instance, may absorb or lose moisture in transit, there may be differences between the weight when packed for shipment, and the weight upon arrival.

FDA should allow for liberal amendments and flexibility to accommodate this type of business uncertainty, particularly where the statute does not mandate the level of detail FDA is proposing. For instance, FDA should permit some fluctuation in quantity (e.g., +/- 2%, etc.) without requiring amendment of a previously filed prior notice.

c. The lot or code numbers or other identifier of the food if applicable

Importers do not typically know the lot numbers of the imported product. This is not information that is provided to them by shippers or suppliers. Moreover, many products do not have lot numbers at all. FDA should at a minimum clarify what is intended by the terms "lot, code, or other identifying number." The requirement is very vague and it is not clear what FDA hopes to gain from such information, particularly where the statute does not require it. Again, FDA should also make clear that the agency will not refuse entry to products for inadequate notice where there is no lot, code or other identifying number to provide. Even if known, some entries will have far more than the four identifiers provided.

f. The anticipated arrival information

The Prior Notice Proposed Rule requires that filers include the port of entry and estimated day and time of arrival. Proposed 21 C.F.R. § 1.288(k)(1), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives 3 hours later or 1 hour earlier than reported in the notice, the Prior Notice Proposed Rule requires that the filer correct the arrival information. Proposed 21 C.F.R. § 1.288(k)(2), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives outside this 4-hour arrival window, the prior notice is inadequate, the product will be refused, and a new prior notice must be made. As NCFIA notes, requiring updates to filed notices when, as is very common, arrival information changes, will necessitate importers and Customs brokers to maintain a 24-hour a day, 7 days a week operations.

The Bioterrorism Act reflects far greater flexibility to accommodate the commercial realities of the food importation business than does the Prior Notice Proposed Rule. The Act states: "Nothing in this section may be construed as a limitation on the port of entry for an article of food." § 307, 21 U.S.C. § 381(m)(1). Congressman Shimkus amplified upon this language:

> Section [307] is not intended as a limitation on the port of entry for an article of food. In some instances, such as inclement weather, routine shipping delays, or natural disasters, a shipment of food may arrive at a port of entry other than the anticipated port of entry provided in the notice. When such situations arise, arrival at a port other than the

> anticipated port should not be the sole basis for invalidating a notice that is otherwise in accordance with the regulations.

Extensions of Remarks of Hon. John Shimkus, Dec. 20, 2001, Cong. Rec. E2389. In short, the Bioterrorism Act specifically provides that FDA may not refuse to admit imported product solely because port of entry information changes due to shipping delays, weather, and the other routine vagaries of the import business. Unlike the statute, the Prior Notice Proposed Rule contemplates no such flexibility.

The Prior Notice Proposed Rule would not, apparently, allow a filer to amend or update a prior notice to change the port of entry, even when the entry port changes due to circumstances that are both very common in the importation business, and completely beyond the control of the filer. Contrary to the plain language of the Bioterrorism Act, FDA would, it seems, not permit the product to enter the United States until the filer submits a new notice. This inflexibility should be remedied in the final rule. Additionally, if Congress and the Act mandate flexibility where the port changes, certainly, similar flexibility is warranted when the time of the product's entry changes, for this information changes far more frequently than does the anticipated port of entry.

Changes to time of entry are very, very common in the importing business; indeed, in the experience of NCFIA's members it far more common for product to enter the United States at a time different than the one scheduled. Truck shipment arrivals vary depending upon weather, traffic, time of day, and day of week. At certain border crossings, at certain times, waits of several hours are not uncommon. Moreover, once a truck driver is in a long line waiting to reach Customs and FDA inspection, the driver may not be able to communicate the change in arrival time and may not know how long the delay will be. Imported product traveling by air encounter similar impossible-to-predict delays and changes.

In addition, for articles of food arriving by sea it is very difficult to know the precise hour the vessel will arrive at the port because reliable information simply does not exist. Shippers typically only notify the importer of the day of arrival, and even then, this information changes frequently. Also, by statute, captains are entitled to divert a vessel to a different port, at his or her sole discretion. This kind of change may not even be communicated to the importer until after or shortly before the vessel arrives at the new port. Notably, in its 24-hour regulation, Customs is satisfied with simply obtaining "the date the vessel is scheduled to arrive at the first U.S. port in Customs territory" for purposes of identifying "high risk" containers.

NCFIA urges FDA to reconsider the arrival requirements and make them far more flexible, as envisioned and mandated in the Bioterrorism Act. Where an article's entry arrival information (port, date, time of day) changes due to routine shipping delays, weather, and other similar circumstances beyond the control of the importer, FDA should not penalize the importer by refusing to admit product. NCFIA further notes that if FDA persists in demanding arrival information that

frequently changes and is not known, then the term "arrival" must be defined to clarify when the article is deemed to have arrived at the port – e.g., when a truck arrives at a border crossing, when a vessel crosses into a United States port, if it is a containerized shipment, the time the container is unloaded, the time the container is scheduled to be picked up, etc.

In addition, if FDA can convincingly demonstrate that detailed arrival information is vital to FDA's identificaiton-for-inspecition functions, than NCFIA suggests that Customs is the much more reliable source for this information. Customs has direct communications with vessels, port authorities, truckers, border crossings, airports and airlines. Customs captures reliable arrival information through these existing communication networks that importers and their brokers do not have. Whatever information FDA receives from importers regarding arrivals, that information is likely to be far less accurate and reliable than what could be obtained through Customs. NCFIA urges FDA to look to Customs for the accurate arrival information the agency believes it needs.

4. The Final Rule Must Clarify Provisions Regarding Identification Of Known Growers

There are numerous issues with the identification of the grower, if known. First, FDA ponders whether it should require grower information for botanicals, unspecified fish and seafood, and processed foods. Nothing in the Bioterrorism Act or its legislative history indicates that FDA should deviate so far from the common sense definition of "grower."

From the Cambridge Dictionary of American English (http://dictionary.cambridge.org/) comes this sensible definition for a plain term:

grow (DEVELOP)
verb [I/T]
to provide (a plant) with the conditions it needs to develop, or to develop from a seed or small plant
This plant grows best in the shade.
We're growing some herbs on the windowsill.

grower
noun [C]
a person or company that cultivates a particular plant or crop in order to sell it
citrus growers

There is no evidence whatsoever that Congress intended to reach beyond this definition of "grower" of plants or crops to require identification of those who catch, harvest, or even cultivate fish, shrimp, and other aquatic products. Aquaculture and commercial fishing are very distinct activities that share little with the traditional practices of growing, farming, and harvesting. If

Congress had intended to cover these types of entities and practices within the grower identification provision of Section 307, 21 U.S.C. § 381(m)(1), it would have done so explicitly.

Nor is there any indication that Congress intended to mandate identification of growers who contribute to processed foods. Requiring grower information for processed foods will lead to absurd results. For example, it would mean that the prior notice for a frozen pie would have to identify the growers of the apples and raisins in the pie, the grower of the wheat in the crust, and the growers of the spices, sugar cane, and cornstarch in the filing. Again, if Congress had intended to require identification of grower beyond the common sense definition of those who cultivate plants and crops, it would have so stated explicitly.

NCFIA notes that to the extent certain plants or processors are suspect, FDA captures this information already through its import alert program. If FDA believes that requiring additional traceback for processed foods and aquaculture products will concretely aid its ability to identify which products to inspect, it should so state. It is not reasonable to place the burden upon industry to explain why FDA does not need such difficult to obtain and unreasonable information.

FDA states that it will provide space for the identification of up to three growers on the prior notice form. 68 Fed. Reg. at 5437, col. 2. This provision for grower identification is inadequate for many types of imported agricultural products. It is not uncommon for a single shipment of agricultural product to commingle the product of numerous, and even hundreds, of growers. Commingling is very common with cocoa beans, coffee beans, grains, certain spices, fresh produce, and other agricultural products. Under such circumstances, NCFIA does not believe FDA should mandate grower identification. The information is extremely burdensome to provide and would not further the inspection mandate of the Bioterrorism Act. Once product is commingled, it is impossible to know, for instance, which grower contributed an individual cocoa or coffee bean or a handful of wheat. If FDA did wish to inspect a particular grower's contribution, it is impossible to segregate that product from the larger, commingled shipment. Under such circumstances, the individual grower(s) contributing to a commingled shipment cannot be known, and therefore should not be identified.

IV. TIMING ISSUES

1. The Required Time For Prior Notice Is Too Long And Impractical

NCFIA has already addressed many of the problems with FDA's proposed requirement of submitting prior notice by noon of the day prior to the article's arrival at port of entry. As discussed above, the assumptions and economic analysis upon which this deadline rests are suspect. Moreover, FDA justifies its noon of day prior to arrival deadline because, after reviewing 64 packages of entry documents it believed that most of the information was available. NCFIA disputes this conclusion. Sixty-four entries can hardly be considered representative when millions of entries

are made each year—it is not known whether these 64 packages of entry documents are representative of all products at various ports of entry around the nation, or whether these documents are representative of the manner in which these products are transported to the various ports of entry. Furthermore, FDA only compared the document invoice date with the date of entry; however, the commercial documents do not contain all information necessary for the filing of prior notice (e.g., ACS number, lot code, the country from which the article is shipped, anticipated arrival information, or carrier information). Further still, FDA's own review reveals that less than half of the entries (48%) had invoice information two or more days prior to the arrival date. Of the remaining entries, 25% had matching invoice and arrival dates, while 27% of these entries had invoice dates that were at least one day prior to the arrival date. Therefore, a considerable number of entries analyzed by FDA could not meet the minimum advanced notice requirement of noon of the calendar day before the day of arrival.

NCFIA urges FDA to consider abandoning the fixed calendar day standard of noon of the day prior to port arrival. Such a standard severely penalizes the filer with delays of up to 36 hours if the prior notice is submitted one minute beyond noon. To avoid this penalty, it is likely that filers will jam the FDA notification system to avoid the noon cut off and penalty, resulting in delays and system overload. In the alternative, NCFIA suggests a rolling notification of four hours prior to estimated arrival time at the port of entry. Adopting a four hour prior notice requirement is closer to current practice and, NCFIA believes, likely to be far less disruptive to trade.

2. FDA's Extremely Limited Amendment Options Would Be Very Burdensome And Costly

The Prior Notice Proposed Rule permits filers to amend previously filed notices only under very limited circumstances. The filer may only amend a previously filed notice to add information not known about a product's identity at the time the notice was first made and only if the filer anticipates and notes, at the time of the original filing, that an amendment will be made in the future. Proposed 21 C.F.R. § 1.290(a), 68 Fed. Reg. at 5462, col. 2, and proposed 21 C.F.R. § 1.288(e)(2), 68 Fed. Reg. at 5461, col. 3. If any of this information is incomplete or inaccurate, the article of food may not enter the United States. Consequently, the accuracy of the many data elements in the notice is crucial. If there is even a single error in the prior notice, it cannot be corrected; the filer must submit a new one.

Among other things, clarification is needed as to what is meant by amendments only for information about a product's identity not known at the time of first filing. Under such an interpretation, FDA would *not* permit amendments to a previously filed notice if information that was "known" at the time of filing has changed, such as product quantity or lot numbers. FDA should clarify that, at a minimum, amendments are permitted to update product identity information, even where the information had been known at the time of filing, but changed.

In addition, the Prior Notice Proposed Rule does not even allow for the correction of errors in a previously filed prior notice. The Prior Notice Proposed Rule requires entry of numerous multi-digit alpha and numeric codes. These same codes are used in the ACS/OASIS system now and simple errors are not uncommon. The Prior Notice Proposed Rule would require entry of even more coded information, with even more opportunity for simple, good faith errors and changes. Yet, there is no provision in the Prior Notice Proposed Rule to allow for error correction. Errors most likely will not come to light until the prior notice does not match up with the product presented at the port of entry. This will result in the product being refused entry and the filing of a new notice, plus attendant costs to the store the product. In the case of perishable product, this may mean the market value of the product is destroyed. Even if the error is discovered in advance, no corrections may be made. The importer must cancel the old notice and file a new one.

NCFIA urges FDA to liberalize the amendments to allow for other changes to a previously filed notice. Without a more realistic approach, FDA's requirements will increase filing burdens and harm the accuracy and utility of the information to be collected. FDA decisions to refuse product, particularly for minor omissions and inaccuracies to information the Bioterrorism Act does not even require, will jam the flow of trade.

V. OTHER ISSUES

1. The Prior Notice Proposed Rule Does Not Allow For Different Modes Of Transportation And Types of Food

21 U.S.C. § 381(m)(2) describes the regulations FDA must promulgate to effect the identification-for-inspection goals of the Bioterrorism Act:

> Regulations ... shall require that a notice ... be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import... In determining the specified period of time required ... [FDA] may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration.

21 U.S.C. § 381(m)(2).

FDA has not, however, customized the Prior Notice Proposed Rule in any way to allow for the many different foods that enter the United States and their manner of arrival. A single set of requirements applies to every shipment, regardless of whether it is an ocean vessel from New

Zealand, a small air container of high-end cheeses and truffles, arriving by air freight from Europe, or a truck's daily crossing into the United States from a Canadian plant an hour from the border crossing. FDA makes no allowance for the differences and challenges that arise depending upon the product being imported and the mode of transportation. A noon of day prior to arrival notice requirement might be reasonable, if adequate allowance is made for amendments, for a trans-Atlantic, ocean-going vessel that is at sea for more than a week. Noon of the previous day, however, is likely to be unworkable for most air cargo as well as companies shipping fresh, frozen, and highly perishable goods from locations within 60 miles of United States land borders.

Not all types of imports pose the same contamination and bioterrorism threats. NCFIA members are participating in a number of programs intended to assure that product is consistent and safe. FDA's Hazard Analysis And Critical Control Points (HAACP) for fish and seafood, for example, is intended to provide documentation of the safety procedures followed to prevent, among other things, product contamination. Customs is also developing the Customs-Trade Partnership Against Terrorism, or C-TPAT, program with importers in order to identify low risk imports and to streamline the importation of such products. FDA, however, makes no such allowances with the Prior Notice Proposed Rule. Every product, it seems, poses the same potential risk of bioterrorist threat.

FDA would do well to look at the problems Customs is experiencing with its initiative to require notification of manifests 24 hours prior to loading. The current rule applies only to vessels and has led to severe interruption in imports by vessel. Customs is wrestling with the implementation of the vessel rule. Significantly, Customs is proposing **separate** rules to deal with shipments by air and by land. Customs is not attempting, as FDA is, to have one rule fit all the modalities and circumstances of import. Products, mode of transport, the relative risks different products present are all too varied, and the vagaries of importation too unpredictable for a single rule to address all these issues without also grinding the global trading system to a halt.

2. The Final Rule Should Clarify What Is "An Article Of Food"

According to the preamble to the proposed rule, "any food product identified by a specific FDA product code and quantity description produced by a single manufacturer (or grower, if fresh) associated with a single entry line number (U.S. Customs entry number plus ACS line number plus OASIS/FDA line number)" is a separate "article of food." 68 Fed. Reg. at 5435. The parenthetical "(or grower, if fresh)" above has created some confusion, because it suggests that, for example, a pallet of bananas from numerous different growers may not be considered a single article of food. We assume that FDA did not intend that result. We note, for instance that this interpretation is at odds with FDA's proposal to allow for the identification of up to three growers on a single prior notice. 68 Fed. Reg. at 5437, col. 2. NCFIA requests that FDA clarify that a shipment containing a single product from multiple grower is nevertheless, a single article of food requiring only one prior notice.

3. FDA Provides No Procedures In the Event Product Is Refused Entry

FDA should address reviewability of FDA's prior notice determinations in the final rule. Currently there is no provision for an administrative appeal of FDA's refusal of a product due to inadequate notice. Furthermore, there are no procedures for how FDA inspectors should handle product refusals, how refused product should be off-loaded and stored, and how and when the importer should be notified.

Rarely is judicial review of agency action not granted to an aggrieved party. The Administrative Procedure Act mandates judicial review of agency action "except to the extent that – (1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). There is virtually a presumption in favor of judicial review unless a contrary purpose is fairly discernable in the statutory scheme. *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967). Agency action typically is found to be non-reviewable only if there is a showing of "clear and convincing evidence" of a legislative intent not to allow review. *Abbott Laboratories*, 387 U.S. at 140 ("To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.")

While the Bioterrorism Act does not expressly provide for review of agency decisions, there is no evidence in the statute or its legislative history to overcome the presumption in favor of review. Accordingly, the final rule should provide a mechanism for review, both administrative review within FDA and judicial review in court, if a product is refused admission because it is from an unregistered foreign facility.

4. FDA Provides No Opportunity To Practice Back Up Systems

NCFIA agrees with FDA's goals of requiring that prior notices be submitted to FDA via a web-based, electronic filing system. However, FDA proposes that it would only accept alternative prior notice by mail, fax or E-mail when the Internet-based system is not functioning; otherwise, filers must use the electronic filing process. 68 Fed. Reg. at 5434-5435. NCFIA suggests that greater flexibility is warranted. Under this proposal, filers will have no way of knowing if this back-up filing system works, or indeed, how to file by any means other than electronically. The first time the Internet system fails is the first opportunity any filer will have to test the alternative filing systems. The final rule should, at a minimum, allow filers to train employees in how file prior notices via a "back-up" method so that they may be prepared in the event of a system failure.

5. The Proposed Prior Notice Filing System Does Not Provide For Any Verification Or Validation

FDA emphasizes that the Prior Notice Filing System will provide only a confirmation that the filer has made a notice; the system will provide no verification that the notice was adequate or the information submitted complete or proper. 68 Fed. Reg. at 5435, col. 1. This proposal is at odds with the Customs 24-hour manifest rule, requiring that a shipper provide notification to Customs of a vessel's manifest 24 hours prior to loading. Customs provides for verification and validation of the information the shipper submits. The Customs' rule recognizes that shippers are relying upon information in the control of others; if Customs discovers that any information field is incorrect or inconsistent, such as the carrier-assigned voyage code, the shipper is notified and given time to correct the deficiency.

FDA's Prior Notice Proposed Rule provides for no such verification. A filer has no way of knowing or confirming that, for instance, the FDA registration numbers of the manufacturer or grower, importer, owner, consignee, and carrier are accurate. The filer must rely upon the different entities to provide this information, and to provide it accurately.

NCFIA further believes that requiring the prior notice to provide the name, address, phone number, fax number, and email address of the manufacturer or grower, importer, owner, consignee, and carrier is exceedingly redundant. If FDA receives each firm's FDA registration number, the agency already has this location and contact information. Moreover, the agency's information is likely to be more accurate and is verifiable. Requiring the filer to submit all this information, which FDA already has, simply increases the likelihood of an error that will not be apparent until FDA refuses to allow an article to enter the United States due to inaccuracies in the prior notice

6. The Foreign Seller Should Be Able to File

In the experience of NCFIA members, many United States buyers want no involvement in the process of importing products. These buyers just want the product to show up at their door. In these situations a foreign seller acts as the importer and will import goods into the United States through a customs broker. The final rule will need to allow the foreign seller or the broker to make the prior notice filing with FDA.

* * *

NCFIA thanks FDA for this opportunity to comment. NCFIA and its members are available to assist FDA in the smooth implementation of this new and challenging requirement.

Sincerely,

Richard H. Koby, Esq.
National Coalition of Food Importing Associations